

August 27, 2021

VIA ECF

The Honorable Julien Xavier Neals, U.S.D.J.
United States District Court
King Fed. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07101

Re: *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*
Civil Action No. 18-3632 (JXN)(LDW) (consolidated)

Dear Judge Neals:

This firm, together with Quinn Emanuel, represents Plaintiff Corcept Therapeutics, Inc. (“Corcept”) in the above-captioned matter. We write in response to Teva’s August 24 letter (D.I. 223). As an initial matter, to the extent that oral argument would be helpful to the Court in deciding the pending motion and cross-motion for summary judgment regarding the ’214 patent, Corcept joins in Teva’s request that the Court schedule oral argument at its convenience. Teva’s request for a trial date “at the Court’s earliest convenience” is premature, however, and is based on a substantial mischaracterization of the history and status of the case. Corcept respectfully submits that the most efficient path forward would be for the Court to first resolve the pending summary judgment motions, and then assess whether trial is even necessary.

By way of background, Corcept is an innovator pharmaceutical company that developed and markets the drug Korlym® for the treatment of certain patients with a rare and debilitating endocrine disorder known as Cushing’s syndrome. While Korlym® is the first and currently the only drug marketed by Corcept, the sales of Korlym® are funding Corcept’s development of several new drug products for conditions including ovarian cancer, prostate cancer, breast cancer, Lou Gehrig’s disease, and certain forms of addiction. In contrast, Teva is the largest generic pharmaceutical company in the world with thousands of marketed products. This litigation started because Teva filed an application with the FDA to market a generic copy of Korlym® prior to the expiration of Corcept’s patents that cover the drug.

There are currently two patents in suit, which in shorthand terms can be referred to as the ’214 patent and the ’216 patent. The ’214 patent is the “last-to-expire” patent – that patent protects certain methods of using Korlym® until June of 2037. Because it is the longest-lasting patent, the ’214 patent has been the main focus of the patent litigation between Corcept and Teva. Indeed, the majority of this litigation concerned Teva’s challenge to the validity of that

patent. Teva chose, however, to also litigate its invalidity defense for the '214 patent before the United States Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB") through a post-grant review proceeding known as a petition for a PGR. The PTAB took up Teva's invalidity challenge, and after a year and a half of litigation, the PTAB issued a Final Written Decision rejecting Teva's invalidity defense and confirming the validity of the '214 patent. *See Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, PGR2019-00048, 2020 WL 6809812 (P.T.A.B. Nov. 18, 2020). Because of the PTAB's decision, Teva is now statutorily estopped from contesting the validity of the '214 patent in this case.

Because Teva's defense regarding the validity of the '214 patent has been rejected by the PTAB, the only issue for the Court to decide regarding that patent is whether Teva's sale of a generic version of Korlym® would infringe the '214 patent. The parties' respective motions for summary judgment on that infringement issue are fully briefed, and, as Corcept believes is clear from those papers, Teva will induce infringement of the '214 patent. *See* D.I. 198; D.I. 209. To the extent that Corcept's motion for summary judgment of infringement is granted, there should be no need to try the issues concerning the earlier-expiring '216 patent.

Teva nonetheless asks that a three-day trial on the '216 patent be scheduled now, purportedly because "Teva has already received final FDA approval to market its generic mifepristone product" and would like to enter the market "as soon as possible." This is a non-sequitur—the lack of a trial date is not stopping Teva from selling its generic mifepristone product. As Teva acknowledges, the FDA approved Teva's generic product in August 2020. Teva has been free to begin selling its generic mifepristone product since that date; in fact, Teva can be selling its generic mifepristone product today if it so chooses – the lack of a trial date is not standing in Teva's way. If Teva actually believed that it did not infringe the '214 patent, it would have launched its generic product already.

Teva also goes to considerable lengths in its letter to improperly accuse Corcept of delaying or failing to streamline this case. Corcept will not provide a point by point response to Teva's misleading and selective recitation of the procedural history of this case. By way of example, however, Teva omits that it delayed the case for months by filing an improper motion to dismiss (which was based entirely on evidence that the Court could not consider) without concurrently filing an answer. Teva further omits that Corcept agreed to drop several patents from the case, including the '348 and '495 patents, in an effort to streamline this litigation and reduce burdens on both the parties and the Court shortly after the PTAB rejected Teva's validity challenge to the later-expiring '214 patent. Unlike Teva, which states on its website that its portfolio of 3,500 products is among the largest of any pharmaceutical company in the world, Corcept markets only one product and surely does not have the same resources as Teva to spend on litigation.

In sum, Teva seems intent on forcing Corcept to spend money and resources on a trial that will likely never be necessary. Corcept respectfully submits the far more efficient path forward—for the parties and the Court—is to first resolve the pending summary judgment motions that the parties spent considerable time, effort, and resources fully briefing, and allow

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the Federal Circuit to affirm the validity of the '214 patent. As set forth above, if Corcept's motion is granted, then there should be no need for a trial at all in this action.

We can be available to further discuss at Your Honor's convenience. Thank you for Your Honor's kind attention to this matter.

Respectfully yours,

A handwritten signature in blue ink that reads "William C. Baton". The signature is written in a cursive, flowing style.

William C. Baton

cc: All counsel (via e-mail)